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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/185,904	11/03/98	ANDERSON C	660088.420

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EXAMINER	
SCHNIZER,H	
ART UNIT	**PAPER NUMBER**
1653	5

DATE MAILED: 12/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

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Office Action Summary	Application No. 09/185,904	Applicant(s) Anderson et al.
	Examiner Holly Schnizer	Group Art Unit 1653

X Responsive to communication(s) filed on *Apr 1, 1999*.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *1-101* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

X Claims *1-101* are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Application/Control Number: 09/185,904

Art Unit: 1653

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-41, drawn to recombinant expression constructs encoding ANT polypeptides, host cells, and methods of expressing the polypeptide, classified in class 435, subclass 320.1.

II. Claims 42-57, drawn to ANT polypeptides, classified in class 530, subclass 300.

III. Claims 58-71, drawn to a method of determining the presence of an ANT polypeptide in a sample, classified in class 435, subclass 7.1 .

IV. Claims 72-74, drawn to a method of isolating ANT from a biological sample, classified in class 530, subclass 412.

V. Claims 75-84 and 94 drawn to a method for identifying an agent that binds to an ANT polypeptide and an assay plate for high throughput screening of candidate agents that bind ANT polypeptide, classified in class 435, subclass 7.1.

VI. Claims 85-93 and 97-100, drawn to an ANT ligand, classified in class 530, subclass 300.

VII. Claims 95-96 drawn to a method of targeting a polypeptide to the mitochondrial membrane, classified in class 435, subclass 317.1.

VIII. Claim 101, drawn to a method of treatment comprising administering a pharmaceutical composition comprising an ANT ligand, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

3. The inventions of Groups I, II, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the expression constructs and host cells of Invention I, the polypeptides of Invention II, and the ligands of Invention III have different biological structures and different functions. In addition, subject matter of each Group is not coextensive and thus the search for each would constitute a serious burden upon the examiner. For example, the expression constructs of Group I would require consideration of its use for processes other than the production of the protein, such as nucleic acid hybridization assay and the protein would required searches of literature wherein the protein was isolated from its source rather than recombinantly produced using the polynucleotide. Thus, Group II requires considerations which are not required in the search for proteins of Group I and Group I requires considerations which are not required in the search for the polynucleotides of Group II. Likewise, the polypeptide of Group II has a different function and is used for different purposes than the ligand of Group VI.

4. The products of Group I are unrelated to the processes of Groups III, IV, and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the expression constructs and host cells of Group I are not made in or used by the screening assays Group III, the method of isolating a polypeptide of Group IV, or the method of treatment using a ligand of Group VIII.

5. Invention I is related to Inventions V and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the expression construct and host cells can be used to produce the ANT polypeptide which is an materially different process than the method of identifying an agent that binds to an ANT polypeptide of Group V and the method of targeting a polypeptide to a mitochondrial membrane of Group VII. Moreover, a search of the processes would require additional considerations of binding conditions and targeting strategies not required in a search for the expression construct and host cells. Such additional considerations would constitute undue burden on the examiner if the different inventions were searched together.

6. The polypeptide of Invention II is related to the method of screening for a polypeptide of Invention III and the method of isolating a polypeptide of Invention IV by virtue that the methods can be used to find and obtain the polypeptide. However, the polypeptide can be made by methods materially distinct from those of Inventions III and IV: such as by expressing the polypeptide using the construct of Invention I. Furthermore, a search of the methods would

require additional considerations not required in the search of the polypeptide such as binding conditions and selection of the appropriate ligand to screen for or isolate the polypeptide. Such additional considerations would constitute undue burden upon the examiner if the different Inventions were searched together.

6. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Group II can be used in a materially different process than that of the method of identifying agents that bind the polypeptide of Group V. For example, the polypeptide can be used to make antibodies.

7. Invention II and Invention VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a polypeptide other than the ANT polypeptide of Group II can be used as a fusion protein in a method of targeting polypeptides to the mitochondrial membrane. In addition, the ANT polypeptide can be used in methods materially distinct from that of Group VII such as in the method of screening for ligands which bind ANT polypeptide of Group V.

7. Inventions II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Invention II can be used to make antibodies which is a materially different process than the process of treatment of Group VIII.

8. The methods of Inventions III, IV, V, VII, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions III, IV, V, VII, and VIII are materially different each from the other because each is practiced with materially different process steps, technical considerations, and reagents and each is practiced to accomplish a distinct goal.

9. Invention VI is related to Inventions III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of screening for an ANT polypeptide and for isolating an ANT polypeptide of Inventions III and IV, respectively, could be practiced with a materially different product. For example, the method of screening could be practiced using an activity assay and the method of isolating the ANT polypeptide could be

practiced using standard anion exchange chromatography techniques. Both of these alternative methods would require materially different products than the ligands of Invention II. In addition, the ligand could be used in a method of treatment of diagnosis which are materially different from the methods of Inventions III and IV.

10. The ligand of Group VI is an independent and distinct invention from the method of screening for agents that bind to an ANT polypeptide of Group V and the method of targeting a polypeptide to the mitochondrial membrane of Group VII, wherein the ligands of Group VI can not be made by nor used in the method of Group V or VII.

11. Inventions VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the ligands of Invention VI can be used in screening assays which are materially different from the method of treatment of Group VIII.

12. Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, the initial requirement of restriction for examination purposes as indicated is proper.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached Monday-Friday from 7:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152. The fax phone number for Official Papers to this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER

Holly Schnizer, Ph.D.
December 1, 1999